

**REMARKS**

Claims 1, 7-10, 14-20, 26-32, 38-40, and 45-46 are pending. Claims 2-6, 11-13, 21-25, 33-37 and 41-44 have been canceled without prejudice and without acquiescence. Claims 1, 26, 27, 31, 32 and 38 have been amended without prejudice and without acquiescence to clarify the claim scope. New claims 45 and 46 have been added. Support for the amendments and new claims can be found in the original pending claims. Applicants retain the right to file any divisional and/or continuation applications from any canceled subject matter. No new matter has been added.

The issues outstanding in this application are as follows:

- Claims 1, 7-20 and 32 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite.
- Claim 13 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite.
- Claim 27 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite.
- Claims 1-9, 15, 17, 20, 26-32 and 34-40 have been rejected under 35 U.S.C. §102(b), as being anticipated by Kruzel et al. (International congress Series (2000), 1195 (Lactoferrin, Structure, Function and Applications), 301-310).
- Claims 1-10, 15, 17, 20, 26, 27 and 31-38 have been rejected under 35 U.S.C. §102(b), as being anticipated by Edde et al. (Am. J. Physiol. Gastrointes. Liver Physiol. 281, G1140-G1150, November 2001).
- Claims 1-10, 15-20, 26-32 and 34-40 have been rejected under 35 U.S.C. §102(b), as being anticipated by Kruzel et al. (US 2001/0056067).
- Claims 1, 2, 7-12 and 17-19 have been rejected under 35 U.S.C. §103(a), as being unpatentable by Van Bree et al. (WO 01/72322).

Applicants respectfully traverse the outstanding rejections and objections, and applicants respectfully request reconsideration and withdrawal thereof in light of the amendments and remarks contained herein.

I. U.S.C. §112, second paragraph

A. Claims 1, 7-20, 27 and 32

Claims 1, 7-20, 27 and 32 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants respectfully traverse.

In order to advance the prosecution of the present application, Applicants have amended without acquiescence and without prejudice claims 1 and 32 to clarify the term "improvement." In view of these amendments, Applicants request withdrawal of the rejection.

B. Claim 13

Claim 13 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants respectfully traverse.

In order to advance the prosecution of the present application, Applicants have canceled claim 13 without acquiescence and without prejudice. The subject matter of claim 13 has been incorporated into independent claim 1. In view of these amendments, Applicants request withdrawal of the rejection.

C. Claim 27

Claim 27 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants respectfully traverse.

In order to advance the prosecution of the present application, Applicants have amended claim 27 without acquiescence and without prejudice to clarify the scope of the claim. In view of these amendments, Applicants request withdrawal of the rejection.

## II. 35 U.S.C. §102(b)

## A. Kruzel et al.

Claims 1-9, 15, 17, 20, 26-32 and 34-40 have been rejected under 35 U.S.C. §102(b), as being anticipated by Kruzel et al. (International congress Series (2000), 1195 (Lactoferrin, Structure, Function and Applications), 301-310). Applicants respectfully traverse.

In order to advance the prosecution of the present invention, Applicants have amended without acquiescence and without prejudice independent claims 1, 26, 27, 31, 32 and 38 to incorporate subject matter related to N-terminal lactoferrin variants. Applicants assert that Kruzel et al. does not identify, mention or suggest the use a composition consisting essentially of N-terminal lactoferrin variants. If the Examiner continues to maintain this rejection, then Examiner is requested to make of record the passage relied upon, or state for the record that no such teaching can be found in the Kruzel. See, *In re Gartside*, 203 F.3d 1305, 53 USPQ2d 1769 (Fed. Cir. 2000).

Thus, in view of the amendments contained herein, Applicants assert that Kruzel et al. do not anticipate independents claim 1, 26, 27, 31 32 and 28, and thus, Applicants respectfully request that the rejection be withdrawn.

## B. Edde et al.

Claims 1-10, 15, 17, 20, 26, 27 and 31-38 have been rejected under 35 U.S.C. §102(b), as being anticipated by Edde et al. (Am. J. Physiol. Gastrointes. Liver Physiol. 281, G1140-G1150, November 2001). Applicants respectfully traverse.

In order to advance the prosecution of the present invention, Applicants have amended without acquiescence and without prejudice independent claims 1, 26, 27, 31, 32 and 38 to incorporate subject matter related to N-terminal lactoferrin variants. Applicants assert that Edde et al. does not identify, mention or suggest the use a composition consisting essentially of N-terminal lactoferrin variants. If the Examiner continues to maintain this rejection, then Examiner is requested to make of record the passage relied upon, or state for the record that no such teaching can be found in the Edde. See, *In re Gartside*, 203 F.3d 1305, 53 USPQ2d 1769 (Fed. Cir. 2000).

Thus, in view of the amendments contained herein, Applicants assert that Edde et al. do not anticipate independent claim 1, 26, 27, 31, 32 and 28, and thus, Applicants respectfully request that the rejection be withdrawn.

C. Kruzel et al.

Claims 1-10, 15-20, 26-32 and 34-40 have been rejected under 35 U.S.C. §102(b), as being anticipated by Kruzel et al. (US 2001/0056067). Applicants respectfully traverse.

In order to advance the prosecution of the present invention, Applicants have amended without acquiescence and without prejudice independent claims 1, 26, 27, 31, 32 and 38 to incorporate subject matter related to N-terminal lactoferrin variants. Applicants assert that Kruzel et al. does not identify, mention or suggest the use a composition consisting essentially of N-terminal lactoferrin variants. If the Examiner continues to maintain this rejection, then Examiner is requested to make of record the passage relied upon, or state for the record that no such teaching can be found in the Kruzel. See, *In re Gartside*, 203 F.3d 1305, 53 USPQ2d 1769 (Fed. Cir. 2000).

Thus, in view of the amendments contained herein, Applicants assert that Kruzel et al. do not anticipate independent claim 1, 26, 27, 31, 32 and 28, and thus, Applicants respectfully request that the rejection be withdrawn.

III. 35 U.S.C. §103(a)

Claims 1, 2, 7-12 and 17-19 have been rejected under 35 U.S.C. §103(a), as being unpatentable by Van Bree et al. (WO 01/72322). Applicants respectfully traverse.

In order to advance the prosecution of the present invention, Applicants have amended without acquiescence and without prejudice independent claim 1 to incorporate the subject matter of related to dependent claim 13, which is not subject to this rejection. Applicants assert that Van Bree et al. do not identify, mention, or suggest the use a lactoferrin composition consisting essentially of at least 1% to about 50% of N-terminal lactoferrin variants. If the Examiner continues to maintain this rejection, then Examiner is requested to make of record the passage relied upon, or state for the record that no such teaching can be

found in the Van Bree. See, *In re Gartside*, 203 F.3d 1305, 53 USPQ2d 1769 (Fed. Cir. 2000).

Thus, in view of the amendments contained herein, Applicants respectfully request that the rejection be withdrawn.

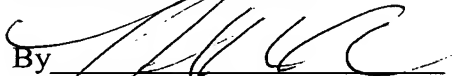
**CONCLUSION**

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Please charge our Deposit Account No. 06-2375 in the amount of \$180.00 for the required fees. If additional fees are due, please charge our Deposit Account No. 06-2375, under Order No. 10315466 from which the undersigned is authorized to draw.

Dated: April 11, 2005

Respectfully submitted,

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